FORM (REV 1	PTO-13	90 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER					
(ALL)	,	RANSMITTAL LETTER TO THE UNITED STATES	112701-305					
		DESIGNATED/ELECTED OFFICE (DO/EO/US)	U.S. APPLICATION NO. OF KNOWN SEE 37 CFR					
		CONCERNING A FILING UNDER 35 U.S.C. 371	07/000420					
INTE		TIONAL APPLICATION NO. INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED					
TITL		PCT/EP00/09444 21 September 2000  NVENTION	22 September 1999					
		D FOR INCREASING PET ACTIVITY						
		T(S) FOR DO/EO/US						
Edu	ardo	SCHIFFRIN and Gail CZARNECKI						
	1	The state of the s						
		herewith submits to the United States Designated/Elected Office (DO/EO/US) the	<u> </u>					
1.	X	This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371						
2. 3.	∐ ⊠	This is a SECOND or SUBSEQUENT submission of items concerning a filir.  This is an express request to begin national examination procedures (35 LLS).						
٥.	23	This is an express request to begin national examination procedures (35 U.S.C examination until the expiration of the applicable time limit set in 35 U.S.C. 3	71(b) and PCT Articles 22 and 39(1).					
4.		A proper Demand for International Preliminary Examination was made by the	19th month from the earliest claimed priority date.					
5.	$\boxtimes$	A copy of the International Application as filed (35 U.S.C. 371 (c) (2))						
gaza,		a.  is transmitted herewith (required only if not transmitted by the Inter-	national Bureau).					
		b. \( \text{ has been transmitted by the International Bureau.} \)	ining Office (DOMIS)					
		c. $\square$ is not required, as the application was filed in the United States Rece A translation of the International Application into English (35 U.S.C. 371(c)(2	` ,					
		A copy of the International Search Report (PCT/ISA/210).	))-					
-8.	$\boxtimes$	Amendments to the claims of the International Application under PCT Article	19 (35 U.S.C. 371 (c)(3))					
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		b. 🛮 have been transmitted by the International Bureau.						
e em,		c. $\square$ have not been made; however, the time limit for making such amend	ments has NOT expired.					
= = =9.		d. have not been made and will not be made.	2.071//200					
9. 10.		A translation of the amendments to the claims under PCT Article 19 (35 U.S.C	3. 371(c)(3)).					
jed:	X	An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).  A copy of the International Preliminary Examination Report (PCT/IPEA/409)						
11. 12.		A translation of the annexes to the International Preliminary Examination Rep						
		(35 U.S.C. 371 (c)(5)).						
	tems 1	3 to 20 below concern document(s) or information included:						
13.		An Information Disclosure Statement under 37 CFR 1.97 and 1.98.						
14.		An assignment document for recording. A separate cover sheet in compliance	with 37 CFR 3.28 and 3.31 is included.					
15. 16.		A FIRST preliminary amendment.						
10. 17.		A SECOND or SUBSEQUENT preliminary amendment.  A substitute specification.						
18.		A change of power of attorney and/or address letter.						
19.	$\boxtimes$	Certificate of Mailing by Express Mail						
20.	$\boxtimes$	Other items or information:						
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21. The following fees are submitted:  BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):  BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):  Neither imperational perlaminary examination fee (37 CFR 1.432) nor and filternational search keport not prepared by the EPO or IPO.  St. 1000.00  International perlaminary examination fee (37 CFR 1.432) not paid to USPTO but information and Search keport not prepared by the EPO or IPO.  International perlaminary examination fee (37 CFR 1.432) not paid to USPTO in the paid to USPTO but information and perlaminary examination fee (37 CFR 1.432) (a) paid to USPTO .  International perlaminary examination fee (37 CFR 1.432) (a) paid to USPTO .  International perlaminary examination fee (37 CFR 1.432) (a) paid to USPTO .  International perlaminary examination fee (37 CFR 1.432) (a) paid to USPTO .  International perlaminary examination fee (37 CFR 1.432) (b) paid to USPTO .  International perlaminary examination fee (37 CFR 1.432) (b) paid to USPTO .  Stochasty of \$1300.00 for furnishing the cash or declaration later than morths from the earliest claimed priority data (37 CFR 1.432 (b)).  Surcharge of \$1300.00 for furnishing the cash or declaration later than morths from the earliest claimed priority data (37 CFR 1.432 (b)).  Surcharge of \$1300.00 for furnishing the English translation later than purpose of the control of the cash o	U.S. A	u.s. application no. if known, see 37 cfr international application no. PCT/EP00/09444							A	TTORNEY'S 1 1127	DOCKET 01-305	NUMBER		
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5):    Neither international perlaimancy examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.45(9)(2) paid to USFTO and laternational Search Report perpared by the EPO or FPO	21.	The fol	lowing	fees are st	ıbmitted:.						CALC	ULATIONS	S PTO U	JSE ONLY
Elementical polluminary examination for 613 CFR 1.482) not paid to USPTO that internation search Report prepared by the PFO or PFO	☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO													
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ENTER APPROPRIATE BASIC FEE AMOUNT = \$860.00  Surcharge of \$13.00 for furnishing the earth or declaration later than months from the eartiest claimed priority date (37 CFR 1.492 (dp.)).  CLAIMS		☐ International preliminary examination fee paid to USPTO (37 CFR 1.482)												
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Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)).  TOTAL NATIONAL FEE = \$1,608.00  Elec for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).  TOTAL FEES ENCLOSED = \$1,608.00  TOTAL FEES ENCLOSED = \$1,608.00  Amount to be: refunded charged \$  A check in the amount of \$1,608.00 to cover the above fees is enclosed.  Please charge my Deposit Account No. in the amount of to cover the above fees.  A duplicate copy of this sheet is enclosed.  The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 02-1818 A duplicate copy of this sheet is enclosed.  NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.  SEND ALL CORRESPONDENCE TO:  Robert M. Barrett, Esq. Bell, Boyd & Lloyd LLC P.O. Box 1135 Tel: (312) 807-4204  Michael S. Leonard NAME  37,557  REGISTRATION NUMBER  May 21, 2001	miust a	lso be filed (	Note 37	CFR 1.9	1.27, 1.28) (c	heck if applicabl	e).							
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# Method for increasing pet activity

#### Field of the invention

This invention relates to a method of increasing the activity of pets; especially elderly cats and dogs.

#### Background of the invention

Once reach an age where their systems start to slow down, certain symptoms of aging begin to manifest themselves; joint stiffness, energy loss, weight gain, increased water intake, digestive system problems, a dull, dry coat and flaky skin. For dogs, this usually starts becoming noticeable at about 5 years for larger breeds and about 7 years for smaller breeds. For cats, this usually starts becoming noticeable at about 7 years. However, the process is different for every animal and there is no standard age at which the symptoms become manifest.

The onset of many of these symptoms may be delayed by feeding the animal a complete, well-balanced diet over its life. Further, the condition of the elderly animal can be improved through nutrition. In particular, healthy animals should be fed a balanced, maintenance food that contains high quality protein, lower amounts of fat to reduce energy intake, dietary fiber, and antioxidants. Also, regular exercise is important to maintain muscle tone, enhance circulation, promote digestion and prevent weight gain.

However, despite good nutrition and regular exercise, many older animals are lethargic and appear to lack energy. Similar problems may also occur in younger animals.

Therefore there remains a need for ways of improving the activity of pets; especially older pets.

#### Summary of the invention

Accordingly, in one aspect, this invention provides a method for improving activity in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.

It has been surprisingly discovered that administering to a pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-

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intestinal tract of the pet results in improved activity levels in the pet. This is particularly noticeable in elderly pets. Without wishing to be bound by theory, it is believed that, amongst other mechanisms, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet produces nutrients and/or increases the absorption of nutrients which provides the pet with better nutrition and more energy. Further, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet reduces the concentrations of pathogenic bacteria in the gastro-intestinal tract and this may improve systemic inflammatory status; leading to less joint stiffness.

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In another aspect, this invention provides a method for ameliorating joint stiffness in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet. The nutritional agent preferably assists in improving – by reducing – the systemic inflammatory status in the pet. This may be achieved by reducing concentrations of pathogenic bacteria known to contribute to an increased inflammatory status.

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The pet is preferably an elderly pet; especially an elderly dog. The dog may be older than 5 years of age; for example older than 7 years of age. The cat may be older than 7 years of age.

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Preferably the nutritional agent is administered to the pet in the form of a complete and nutritionally balanced pet food.

The nutritional agent may be a prebiotic, a probiotic micro-organism, or a fermentation product obtained from the fermentation of probiotic micro-organisms.

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In this specification:-

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"Prebiotic" means a substance or compound which is fermented by the intestinal flora of the pet and hence promotes the growth or development of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet at the expense of pathogenic bacteria. The result of this fermentation is a release of fatty acids, in particular short-chain fatty acids in the colon. This has the effect of reducing the pH value in the colon.

"Probiotic micro-organism" means a micro-organism which beneficially affects a host by improving its intestinal microbial balance (Fuller, R; 1989; <u>J. Applied Bacteriology</u>, 66: 365-378). In general, probiotic micro-organisms produce organic acids such as lactic acid and acetic acid which inhibit the growth of pathogenic bacteria such as *Clostridium perfringens* and *Helicobacter pylori*.

#### Detailed description of preferred embodiments of the invention.

This invention is based upon the discovery that the activity levels in a pet may be improved by administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet. The activity levels of elderly pets, such as elderly dogs, is particularly improved.

The nutritional agent may be a prebiotic, a probiotic micro-organism, or a fermentation product obtained from fermentation of a probiotic micro-organism. Further, combinations of the prebiotics, probiotic micro-organisms and fermentation products may be administered to the pet.

Suitable prebiotics include oligosaccharides, such as inulin and its hydrolysis products commonly known as fructooligosaccharides, galactooligosaccarides, xylo-oligosaccharides or oligo derivatives of starch. Combinations of starches and gums may also be used.

The prebiotics may be provided in any suitable form. For example, the prebiotic may be provided in the form of plant material which contains the prebiotic. Suitable plant materials includes asparagus, artichokes, onions, wheat, yacon or chicory, or residues of these plant materials. Alternatively, the prebiotic may be provided as an inulin extract. Extracts from chicory are particularly suitable. Suitable inulin extracts may be obtained from Orafti SA of Tirlemont 3300, Belgium under the trade mark "Raftiline". For example, the inulin may be provided in the form of Raftiline®ST which is a fine white powder which contains about 90 to about 94% by weight of inulin, up to about 4% by weight of glucose and fructose, and about 4 to 9% by weight of sucrose. Alternatively, the prebiotic may be in the form of a fructooligosaccharide such as obtained from Orafti SA of Tirlemont 3300, Belgium under the trade mark "Raftilose". For example, the inulin may be provided in the form of Raftilose®P95. Otherwise, the fructooligosaccharides may be obtained by hydrolyzing inulin, by enzymatic methods, or by using micro-organisms.

The probiotic micro-organism may be selected from one or more microorganisms suitable for animal consumption and which is able to improve the microbial balance in the intestine.

Examples of suitable probiotic micro-organisms include yeasts such as Saccharomyces, Debaromyces, Candida, Pichia and Torulopsis, moulds such as Aspergillus, Rhizopus, Mucor, and Penicillium and Torulopsis and bacteria such as the genera Bifidobacterium, Bacteroides, Fusobacterium, Melissococcus,

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Propionibacterium, Streptococcus, Enterococcus, Lactococcus, Staphylococcus, Peptostrepococcus, Bacillus, Pediococcus, Micrococcus, Leuconostoc, Weissella, Aerococcus, Oenococcus and Lactobacillus. Specific examples of suitable probiotic micro-organisms are: Saccharomyces cereviseae, Bacillus coagulans, Bacillus licheniformis, Bacillus subtilis, Bifidobacterium bifidum, Bifidobacterium infantis, Bifidobacterium longum, Enterococcus faecium, Enterococcus faecalis, Lactobacillus acidophilus, Lactobacillus alimentarius, Lactobacillus casei subsp. casei, Lactobacillus casei Shirota, Lactobacillus curvatus, Lactobacillus delbruckii subsp. lactis, Lactobacillus farciminus, Lactobacillus gasseri, Lactobacillus helveticus, Lactobacillus johnsonii, Lactobacillus reuteri, Lactobacillus rhamnosus (Lactobacillus GG), Lactobacillus sake, Lactococcus lactis, Micrococcus varians, Pediococcus acidilactici, Pediococcus pentosaceus, Pediococcus acidilactici, Pediococcus halophilus, Streptococcus faecalis, Streptococcus thermophilus, Staphylococcus carnosus, and Staphylococcus xylosus. The probiotic micro-organisms may be in powdered, dried form; especially in spore form for micro-organisms which form spores. Further, if desired, the probiotic micro-organism may be encapsulated to further increase the probability of survival; for example in a sugar matrix, fat matrix or polysaccharide matrix.

The nutritional agent may be administered to the pet as a supplement to the pet's normal diet or as a component of a nutritionally complete pet food. It is preferred to include the nutritional agent in a nutritionally complete pet food.

The nutritionally complete pet food may be in any suitable form; for example in dried form, semi-moist form and wet form. These pet foods may be produced as is conventional. Apart from the nutritional agent, these pet foods may include any one or more of a starch source, a protein source and lipid source. Suitable starch sources are, for example, grains and legumes such as corn, rice, wheat, barley, oats, soy, and mixtures of these. Suitable protein sources may be selected from any suitable animal or vegetable protein source; for example meat and meal, poultry meal, fish meal, soy protein concentrates, milk proteins, gluten, and the like. For elderly animals, it is preferred for the protein source to contain a high quality protein. Suitable lipid sources include meats, animal fats and vegetable fats. The choice of the starch, protein and lipid sources will be largely determined by the nutritional needs of the animal, palatability considerations, and the type of product produced. Further, various other ingredients, for example, sugar, salt, spices, seasonings, vitamins, minerals,

flavoring agents, fats and the like may also be incorporated into the pet food as desired.

For elderly pets, the pet food preferably contains proportionally less fat than pet foods for younger pets. Further, the starch sources may include one or more of rice, barley, wheat and corn.

For dried pet foods a suitable process is extrusion cooking, although baking and other suitable processes may be used. When extrusion cooked, the dried pet food is usually provided in the form of a kibble. If a prebiotic is used, the prebiotic may be admixed with the other ingredients of the dried pet food prior to processing. A suitable process is described in European patent application No 0850569; the disclosure of which is incorporated by reference. If a probiotic micro-organism is used, the organism is best coated onto or filled into the dried pet food. A suitable process is described in European patent application No 0862863; the disclosure of which is incorporated by reference.

For wet foods, the processes described in US patents 4,781,939 and 5,132,137 may be used to produce simulated meat products. The disclosures of these patents are incorporated by reference. Other procedures for producing chunk type products may also be used; for example cooking in a steam oven. Alternatively, loaf type products may be produced by emulsifying a suitable meat material to produce a meat emulsion, adding a suitable gelling agent, and heating the meat emulsion prior to filling into cans or other containers.

The maximum level of prebiotic in the pet food is preferably about 20% by weight; especially about 10% by weight. However, considerably lower levels are found to be effective in increasing activity levels. For example, the prebiotic may comprise about 0.1% to about 5% by weight of the pet food. For pet foods which use chicory as the prebiotic, the chicory may be included to comprise about 0.5% to about 10% by weight of the feed mixture; more preferably about 1% to about 5% by weight.

If a probiotic micro-organism is used, the pet food preferably contains about  $10^4$  to about  $10^{10}$  cells of the probiotic micro-organism per gram of the pet food; more preferably about  $10^6$  to about  $10^8$  cells of the probiotic micro-organism per gram. The pet food may contain about 0.25% to about 20% by weight of the mixture of the probiotic micro-organism; preferably about 0.5% to about 6% by weight; for example about 3% to about 6% by weight.

The pet foods may contain other active agents such as long chain fatty acids. Suitable long chain fatty acids include alpha-linoleic acid, gamma

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linolenic acid, linoleic acid, eicosapentanoic acid, and docosahexanoic acid. Fish oils are a suitable source of eicosapentanoic acids and docosahexanoic acid. Borage oil, blackcurrent seed oil and evening primrose oil are suitable sources of gamma linolenic acid. Safflower oils, sunflower oils, corn oils and soy bean oils are suitable sources of linoleic acid.

If necessary, the pet foods are supplemented with minerals and vitamins so that they are nutritionally complete.

The amount of the pet food to be consumed by the pet to obtain a beneficial effect will depend upon the size or the pet, the type of pet, and age of the pet. However an amount of the pet food to provide a daily amount of about 1g to about 100g of prebiotic, or about  $10^6$  to about  $10^{12}$  cells of the probiotic microorganism, would usually be adequate.

Numerous modifications may be made to the embodiments described above without departing from the scope of the invention. Specific examples recording the remarkable effects of feeding an embodiment of the inventive diet according to the invention to elderly pets are now described for further illustration.

#### Example 1

- A first pet owner in Pretoria, South Africa has two golden retrievers, ages 8 and 9 years. She regarded them as forming an integral part of her family unit and consequently used to provide what she considered the best nutrition available a conventional senior food from a veterinary brand. Nevertheless she observed that her dogs had poor coat quality and had the decreased activity typical of senior dogs. The owner states that she started feeding her dogs the petfood sold under the brand name Olympic Senior (this is a dry dog food containing an effective amount of inulin prebiotic). She reports having since seen the following changes in her dogs:
  - shinier coats,
- a healthy look and,
  - a return to being as lively as they had been a few years previously.

#### 35 Example 2

A second pet owner in South Africa reports having an elderly Staffordshire Terrier which was arthritic, moved slowly and was much less active than when

<sup>&</sup>quot;Olympic" is a trade mark belonging to Epol (Proprietary) Limited.

younger. In particular, it would not run around. The owner started feeding it a diet of Olympic Senior dry dog food, the same as in Example 1. Within a few months, the dog's activity levels increased, it began again to run around and is reportedly now willing and able to jump over a three foot fence.

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#### Example 3

A pet owner in Great Britain reported having an elderly Labrador Retriever which was "very arthritic" and had trouble walking up stairs. She began feeding her dog Winalot Complete Digestion+, a dry dog food containing about 1% chicory as a source of the prebiotic, inulin. Within a month on the product, the dog started running around "like a puppy" and "is now bounding up the stairs so fast that he trips over his own feet".

"Winalot" is a trade mark belonging to Societé de Produits Nestlé of Switzerland.

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#### Example 4

A pet owner in California, USA reports that, after changing his dog's diet to Alpo Complete dry dog food containing about 1% chicory by weight (ALPO is a trade mark of Societé de Produits Nestlé), its coat became noticeably shinier, its eyes brighter and its overall activity levels increased.

A dog owner in Pennsylvania reported similarly that his dog, after changing to a diet of Alpo Complete soon exhibited remarkably improved changes in looks and in "attitude", while a dog owner in West Virginia observed that his dog no long behaved in accordance with its 13 years, but instead seemed far younger.

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#### Claims

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- 1. A method for improving activity in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
  - 2. A method according to claim 1 in which the nutritional agent is a component of a nutritionally complete pet food.
- A method according to claim 1 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
  - 4. A method according to claim 3 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
  - 5. A method according to claim 1 in which the pet food further comprises a long chain fatty acid.
- A method according to claim 1 in which the pet food further comprises a starch source selected from one or more of corn, rice, barley, and wheat.
- A method for improving activity in an elderly pet, the method comprising administering to the pet a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
  - 8. A method according to claim 7 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
  - 9. A method according to claim 8 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
- 10. A method according to claim 7 in which the pet food contains about 0.1% to about 5% by weight of a prebiotic as the nutritional agent.

- 11. A method according to Claim 7 in which the pet food contains about  $10^4$  to about  $10^{10}$  cells of a probiotic micro-organism per gram of the pet food as the nutritional agent.
- 12. A method according to Claim 7 in which the pet food further comprises a long chain fatty acid.
  - 13. A method according to Claim 1 in which the pet food further comprises a starch source selected from one or more of corn, rice, barley, and wheat.
  - 14. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the dog.
    - 15. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the dog.
    - 16. A method for ameliorating joint stiffness in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
- 17. A method according to Claim 16 wherein the nutritional agent assists in 20 improving systemic inflammatory status in a pet.
  - 18. A method according to Claim 17 wherein the nutritional agent assists in reducing concentrations of pathogenic bacteria known to contribute to an increased inflammatory status.
    - 19. A method according to Claim 16 in which the pet is an elderly dog.
- 25 20. A method according to Claim 16 in which the pet is an elderly cat.

- 21. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a prebiotic selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
- 5 22. A method of providing a pet with more energy comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
  - 23. A method of improving physical activity in an elderly pet comprising administering to the pet a pet food composition comprising about 1% chicory by weight.
- 24. A method of improving physical activity levels in an elderly pet comprising administering to the pet a pet food composition comprising at least about 1% chicory by weight as a source of inulin.
  - 25. A method of increasing activity level in a pet of at least 5 years of age, comprising feeding the pet a balanced diet comprising a pet food formulation comprising inulin in an effective amount to reduce joint stiffness.
  - 26. A method of returning a senior pet to a previous level of liveliness, comprising administering to the pet a pet food composition comprising inulin in an amount effective to increase physical activity in such pet.

### **ABSTRACT**

A method for improving activity in a pet; especially elderly cats and dogs. The pets are administered a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of a pet. The nutritional agent may be a prebiotic or a probiotic micro-organism, or both.

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## Method for increasing pet activity

#### Field of the invention

This invention relates to a method of increasing the activity of pets; especially elderly cats and dogs.

#### Background of the invention

Once reach an age where their systems start to slow down, certain symptoms of aging begin to manifest themselves; joint stiffness, energy loss, weight gain, increased water intake, digestive system problems, a dull, dry coat and flaky skin. For dogs, this usually starts becoming noticeable at about 5 years for larger breeds and about 7 years for smaller breeds. For cats, this usually starts becoming noticeable at about 7 years. However, the process is different for every animal and there is no standard age at which the symptoms become manifest.

The onset of many of these symptoms may be delayed by feeding the animal a complete, well-balanced diet over its life. Further, the condition of the elderly animal can be improved through nutrition. In particular, healthy animals should be fed a balanced, maintenance food that contains high quality protein, lower amounts of fat to reduce energy intake, dietary fiber, and antioxidants. Also, regular exercise is important to maintain muscle tone, enhance circulation, promote digestion and prevent weight gain.

However, despite good nutrition and regular exercise, many older animals are lethargic and appear to lack energy. Similar problems may also occur in younger animals.

Therefore there remains a need for ways of improving the activity of pets; especially older pets.

#### Summary of the invention

Accordingly, in one aspect, this invention provides a method for improving activity in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastrointestinal tract of the pet.

It has been surprisingly discovered that administering to a pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-

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intestinal tract of the pet results in improved activity levels in the pet. This is particularly noticeable in elderly pets. Without wishing to be bound by theory, it is believed that, amongst other mechanisms, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet produces nutrients and/or increases the absorption of nutrients which provides the pet with better nutrition and more energy. Further, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet reduces the concentrations of pathogenic bacteria in the gastro-intestinal tract and this may improve systemic inflammatory status; leading to less joint stiffness.

In another aspect, this invention provides a method for ameliorating joint stiffness in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet. The nutritional agent preferably assists in improving – by reducing – the systemic inflammatory status in the pet. This may be achieved by reducing concentrations of pathogenic bacteria known to contribute to an increased inflammatory status.

The pet is preferably an elderly pet; especially an elderly dog. The dog may be older than 5 years of age; for example older than 7 years of age. The cat may be older than 7 years of age.

Preferably the nutritional agent is administered to the pet in the form of a complete and nutritionally balanced pet food.

The nutritional agent may be a prebiotic, a probiotic micro-organism, or a fermentation product obtained from the fermentation of probiotic micro-organisms.

In this specification:-

"Prebiotic" means a substance or compound which is fermented by the intestinal flora of the pet and hence promotes the growth or development of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet at the expense of pathogenic bacteria. The result of this fermentation is a release of fatty acids, in particular short-chain fatty acids in the colon. This has the effect of reducing the pH value in the colon.

"Probiotic micro-organism" means a micro-organism which beneficially affects a host by improving its intestinal microbial balance (Fuller, R; 1989; <u>J. Applied Bacteriology</u>, 66: 365-378). In general, probiotic micro-organisms produce organic acids such as lactic acid and acetic acid which inhibit the growth of pathogenic bacteria such as *Clostridium perfringens* and *Helicobacter pylori*.

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#### Detailed description of preferred embodiments of the invention.

This invention is based upon the discovery that the activity levels in a pet may be improved by administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet. The activity levels of elderly pets, such as elderly dogs, is particularly improved.

The nutritional agent may be a prebiotic, a probiotic micro-organism, or a fermentation product obtained from fermentation of a probiotic micro-organism. Further, combinations of the prebiotics, probiotic micro-organisms and fermentation products may be administered to the pet.

Suitable prebiotics include oligosaccharides, such as inulin and its hydrolysis products commonly known as fructooligosaccharides, galactooligosaccarides, xylo-oligosaccharides or oligo derivatives of starch. Combinations of starches and gums may also be used.

The prebiotics may be provided in any suitable form. For example, the prebiotic may be provided in the form of plant material which contains the prebiotic. Suitable plant materials includes asparagus, artichokes, onions, wheat, yacon or chicory, or residues of these plant materials. Alternatively, the prebiotic may be provided as an inulin extract. Extracts from chicory are particularly suitable. Suitable inulin extracts may be obtained from Orafti SA of Tirlemont 3300, Belgium under the trade mark "Raftiline". For example, the inulin may be provided in the form of Raftiline®ST which is a fine white powder which contains about 90 to about 94% by weight of inulin, up to about 4% by weight of glucose and fructose, and about 4 to 9% by weight of sucrose. Alternatively, the prebiotic may be in the form of a fructooligosaccharide such as obtained from Orafti SA of Tirlemont 3300, Belgium under the trade mark "Raftilose". For example, the inulin may be provided in the form of Raftilose®P95. Otherwise, the fructooligosaccharides may be obtained by hydrolyzing inulin, by enzymatic methods, or by using micro-organisms.

The probiotic micro-organism may be selected from one or more microorganisms suitable for animal consumption and which is able to improve the microbial balance in the intestine.

Examples of suitable probiotic micro-organisms include yeasts such as Saccharomyces, Debaromyces, Candida, Pichia and Torulopsis, moulds such as Aspergillus, Rhizopus, Mucor, and Penicillium and Torulopsis and bacteria such as the genera Bifidobacterium, Bacteroides, Fusobacterium, Melissococcus,

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Propionibacterium, Streptococcus, Enterococcus, Lactococcus, Staphylococcus, Peptostrepococcus, Bacillus, Pediococcus, Micrococcus, Leuconostoc, Weissella, Aerococcus, Oenococcus and Lactobacillus. Specific examples of suitable probiotic micro-organisms are: Saccharomyces cereviseae, Bacillus coagulans, Bacillus licheniformis, Bacillus subtilis, Bifidobacterium bifidum, Bifidobacterium infantis, Bifidobacterium longum, Enterococcus faecium, Enterococcus faecalis, Lactobacillus acidophilus, Lactobacillus alimentarius, Lactobacillus casei subsp. casei, Lactobacillus casei Shirota, Lactobacillus curvatus, Lactobacillus delbruckii subsp. lactis, Lactobacillus farciminus, Lactobacillus gasseri, Lactobacillus helveticus, Lactobacillus johnsonii, Lactobacillus reuteri, Lactobacillus rhamnosus (Lactobacillus GG), Lactobacillus sake, Lactococcus lactis, Micrococcus varians, Pediococcus acidilactici, Pediococcus pentosaceus, Pediococcus acidilactici, Pediococcus halophilus, Streptococcus faecalis, Streptococcus thermophilus, Staphylococcus carnosus, and Staphylococcus xylosus. The probiotic micro-organisms may be in powdered, dried form; especially in spore form for micro-organisms which form spores. Further, if desired, the probiotic micro-organism may be encapsulated to further increase the probability of survival; for example in a sugar matrix, fat matrix or polysaccharide matrix.

The nutritional agent may be administered to the pet as a supplement to the pet's normal diet or as a component of a nutritionally complete pet food. It is preferred to include the nutritional agent in a nutritionally complete pet food.

The nutritionally complete pet food may be in any suitable form; for example in dried form, semi-moist form and wet form. These pet foods may be produced as is conventional. Apart from the nutritional agent, these pet foods may include any one or more of a starch source, a protein source and lipid source. Suitable starch sources are, for example, grains and legumes such as corn, rice, wheat, barley, oats, soy, and mixtures of these. Suitable protein sources may be selected from any suitable animal or vegetable protein source; for example meat and meal, poultry meal, fish meal, soy protein concentrates, milk proteins, gluten, and the like. For elderly animals, it is preferred for the protein source to contain a high quality protein. Suitable lipid sources include meats, animal fats and vegetable fats. The choice of the starch, protein and lipid sources will be largely determined by the nutritional needs of the animal, palatability considerations, and the type of product produced. Further, various other ingredients, for example, sugar, salt, spices, seasonings, vitamins, minerals,

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flavoring agents, fats and the like may also be incorporated into the pet food as desired.

For elderly pets, the pet food preferably contains proportionally less fat than pet foods for younger pets. Further, the starch sources may include one or more of rice, barley, wheat and corn.

For dried pet foods a suitable process is extrusion cooking, although baking and other suitable processes may be used. When extrusion cooked, the dried pet food is usually provided in the form of a kibble. If a prebiotic is used, the prebiotic may be admixed with the other ingredients of the dried pet food prior to processing. A suitable process is described in European patent application No 0850569; the disclosure of which is incorporated by reference. If a probiotic micro-organism is used, the organism is best coated onto or filled into the dried pet food. A suitable process is described in European patent application No 0862863; the disclosure of which is incorporated by reference.

For wet foods, the processes described in US patents 4,781,939 and 5.132.137 may be used to produce simulated meat products. The disclosures of these patents are incorporated by reference. Other procedures for producing chunk type products may also be used; for example cooking in a steam oven. Alternatively, loaf type products may be produced by emulsifying a suitable meat material to produce a meat emulsion, adding a suitable gelling agent, and heating the meat emulsion prior to filling into cans or other containers.

The maximum level of prebiotic in the pet food is preferably about 20% by weight; especially about 10% by weight. However, considerably lower levels are found to be effective in increasing activity levels. For example, the prebiotic may comprise about 0.1% to about 5% by weight of the pet food. For pet foods which use chicory as the prebiotic, the chicory may be included to comprise about 0.5% to about 10% by weight of the feed mixture; more preferably about 1% to about 5% by weight.

If a probiotic micro-organism is used, the pet food preferably contains about 10<sup>4</sup> to about 10<sup>10</sup> cells of the probiotic micro-organism per gram of the pet food; more preferably about 10<sup>6</sup> to about 10<sup>8</sup> cells of the probiotic microorganism per gram. The pet food may contain about 0.25% to about 20% by weight of the mixture of the probiotic micro-organism; preferably about 0.5% to about 6% by weight; for example about 3% to about 6% by weight.

The pet foods may contain other active agents such as long chain fatty acids. Suitable long chain fatty acids include alpha-linoleic acid, gamma

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linolenic acid, linoleic acid, eicosapentanoic acid, and docosahexanoic acid. Fish oils are a suitable source of eicosapentanoic acids and docosahexanoic acid. Borage oil, blackcurrent seed oil and evening primrose oil are suitable sources of gamma linolenic acid. Safflower oils, sunflower oils, corn oils and soy bean oils are suitable sources of linoleic acid.

If necessary, the pet foods are supplemented with minerals and vitamins so that they are nutritionally complete.

The amount of the pet food to be consumed by the pet to obtain a beneficial effect will depend upon the size or the pet, the type of pet, and age of the pet. However an amount of the pet food to provide a daily amount of about 1g to about 100g of prebiotic, or about 10<sup>6</sup> to about 10<sup>12</sup> cells of the probiotic microorganism, would usually be adequate.

Numerous modifications may be made to the embodiments described above without departing from the scope of the invention. Specific examples recording the remarkable effects of feeding an embodiment of the inventive diet according to the invention to elderly pets are now described for further illustration.

#### Example 1

A first pet owner in Pretoria, South Africa has two golden retrievers, ages 8 and 9 years. She regarded them as forming an integral part of her family unit and consequently used to provide what she considered the best nutrition available - a conventional senior food from a veterinary brand. Nevertheless she observed that her dogs had poor coat quality and had the decreased activity typical of senior dogs. The owner states that she started feeding her dogs the petfood sold under the brand name Olympic Senior (this is a dry dog food containing an effective amount of inulin prebiotic). She reports having since seen the following changes in her dogs:

- shinier coats.
- a healthy look and,
  - a return to being as lively as they had been a few years previously.

"Olympic" is a trade mark belonging to Epol (Proprietary) Limited.

#### 35 Example 2

A second pet owner in South Africa reports having an elderly Staffordshire Terrier which was arthritic, moved slowly and was much less active than when younger. In particular, it would not run around. The owner started feeding it a diet of Olympic Senior dry dog food, the same as in Example 1. Within a few months, the dog's activity levels increased, it began again to run around and is reportedly now willing and able to jump over a three foot fence.

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#### Example 3

A pet owner in Great Britain reported having an elderly Labrador Retriever which was "very arthritic" and had trouble walking up stairs. She began feeding her dog Winalot Complete Digestion+, a dry dog food containing about 1% chicory as a source of the prebiotic, inulin. Within a month on the product, the dog started running around "like a puppy" and "is now bounding up the stairs so fast that he trips over his own feet".

"Winalot" is a trade mark belonging to Societé de Produits Nestlé of Switzerland.

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#### Example 4

A pet owner in California, USA reports that, after changing his dog's diet to Alpo Complete dry dog food containing about 1% chicory by weight (ALPO is a trade mark of Societé de Produits Nestlé), its coat became noticeably shinier, its eyes brighter and its overall activity levels increased.

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A dog owner in Pennsylvania reported similarly that his dog, after changing to a diet of Alpo Complete soon exhibited remarkably improved changes in looks and in "attitude", while a dog owner in West Virginia observed that his dog no long behaved in accordance with its 13 years, but instead seemed far younger.

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#### **Claims**

- 1. A method for improving activity in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
- 2. A method according to claim 1 in which the nutritional agent is a component of a nutritionally complete pet food.
- A method according to claim 1 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
  - 4. A method according to claim 3 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
  - 5. A method according to claim 1 in which the pet food further comprises a long chain fatty acid.
- A method according to claim 1 in which the pet food further comprises a starch source selected from one or more of corn, rice, barley, and wheat.
  - 7. A method for improving activity in an elderly pet, the method comprising administering to the pet a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
    - 8. A method according to claim 7 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
    - 9. A method according to claim 8 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
- 10. A method according to claim 7 in which the pet food contains about 0.1% to about 5% by weight of a prebiotic as the nutritional agent.

- 11. A method according to claim 7 in which the pet food contains about 10<sup>4</sup> to about 10<sup>10</sup> cells of a probiotic micro-organism per gram of the pet food as the nutritional agent.
- 12. A method according to claim 7 in which the pet food further comprises a long chain fatty acid.
- 13. A method according to claim 1 in which the pet food further comprises a starch source selected from one or more of corn, rice, barley, and wheat.
  - 14. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the dog.
  - 15. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the dog.
  - 16. A method for ameliorating joint stiffness in a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
- 25 17. A method according to claim 16 wherein the nutritional agent assists in improving systemic inflammatory status in the pet.
  - 18. A method according to claim 17 wherein the nutritional agent assists in reducing concentrations of pathogenic bacteria known to contribute to an increased inflammatory status.
  - 19. A method according to any one of claims 16 to 18 in which the pet is an elderly dog.
- 35 20. A method according to any one of claims 16 to 18 in which the pet is an elderly cat.

21. A method for improving activity in an elderly dog, the method comprising administering to the dog a nutritionally complete pet food which contains a prebiotic selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.

Docket	No.
112701	-305

# **Declaration and Power of Attorney For Patent Application English Language Declaration**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original,

(Number)	(Country)	(Day/Month/Year Filed)	
(Number)	(Country)	(Day/Month/Year Filed)	
PCT/EP00/09444 (Number)	(Country)	21 September 2000 (Day/Month/Year Filed)	
Prior Foreign Application	Priority Not Claimed		
I acknowledge the duty known to me to be m Section 1.56.  I hereby claim foreign Section 365(b) of any any PCT International listed below and have	ve reviewed and under amended by any amended by any amended to the Urnaterial to patentability priority benefits und foreign application(s) application which designates identified below, the PCT International apprince and the second	(if applicable) erstand the contents of the above is endment referred to above.  Inited States Patent and Trademark of as defined in Title 37, Code of the above of the above.  Title 35, United States Code, for patent or inventor's certificate and at least one country other the above of the	Section 119(a)-(d) or, or Section 365(a) of than the United States, oplication for patent or
the specification of which (check one)  ☐ is attached hereto.  ☐ was filed on May 2  Application Number	1, 2001	_ as United States Application No.	or PCT International
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insofar as the subject matter of united States or PCT Internation U.S.C. Section 112, I acknowled Office all information known to r	each of the claims of this ap al application in the manner p ge the duty to disclose to the me to be material to patental able between the filing date of	plication is not disclosed in the prior provided by the first paragraph of 35 United States Patent and Trademark bility as defined in Title 37, C. F. R., the prior application and the national
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: 'As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)



Send Correspondence to: Robert M. Barrett

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Gail Czarnecki	
Second inventors signature Samecki - Mauldu	Jugust 2, 2001
Residence Easton, Missouri	
Citizenship USA	
Post Office Address 3550 Southeast 95th Street	
Easton, Missouri 64443	

Page 1 of 3

Docket No. 112701-305

# Declaration and Power of Attorney For Patent Application English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD FOR INCREASING PET ACTIVITY

the specification of w	hich						
(check one)							
•							
is attached hereto		Linite d Chatan Application No.	or DCT International				
★ was filed on May		as United States Application No.	OF FOT International				
Application Numb							
and was amende	d on		<u> </u>				
		(if applicable)					
		estand the contents of the above in ndment referred to above.	dentified specification,				
I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations Section 1.56.							
I hereby claim foreig Section 365(b) of an any PCT International listed below and have	gn priority benefits unde by foreign application(s) t al application which desig e also identified below, by or PCT International appl	er Title 35, United States Code, for patent or inventor's certificate nated at least one country other to checking the box, any foreign a lication having a filing date before	Section 119(a)-(d) or , or Section 365(a) of han the United States, pplication for patent or				
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I hereby claim foreig Section 365(b) of an any PCT International listed below and have inventor's certificate on on which priority is claim. Prior Foreign Application	gn priority benefits underly foreign application(s) foreign application(s) for application which designs also identified below, by or PCT International application(s)  WIPO	er Title 35, United States Code, for patent or inventor's certificate nated at least one country other to y checking the box, any foreign a lication having a filing date before	Section 119(a)-(d) or consection 365(a) of han the United States, pplication for patent or that of the application Priority Not Claimed				

1	hereby	claim	the	benefit	under	35	U.S.C.	Section	119(e)	of	any	United	States	provisional
a	pplicatio	n(s) lis	ted b	elow:										

60/155,451	22 September 1999
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Patent and Trademark Office-U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)



Send Correspondence to: Robert M. Barrett Bell, Boyd & Lloyd LLC P.O. Box 1135 .... Chicago, Illinois 60690-1135 Direct Telephone Calls to: (name and telephone number) Robert M. Barrett (312) 807-4204 Full name of sole or first inventor Eduardo Schiffrin Sole or first inventor's signature 2001.08.09 Residence Q. Crissier, Switzerland Fi. Citizenship Argentina Post Office Address Chemin de Riant-Mont 17 CH-1023 Crissier, Switzerland Full name of second inventor, if any Gail Czarnecki Second inventor's signature Residence Easton, Missouri Citizenship **USA** Post Office Address 3550 Southeast 95th Street Easton, Missouri 64443

Form PTO-SB-01 (6-95) (Modified)